AT

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,924	06/19/2000	JOHN LESLIE ATWELL	674537-2001	6289

20999 7590 06/30/2004

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/581,921	HAMSTROM ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-83 and 90-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *103-105* is/are allowed.

6)☒ Claim(s) *65-83, 90, 91, 102* is/are rejected.

7)☒ Claim(s) *92-101* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 65, 66, 68, 69, 72, 73, 75, 77, 79, 80 , 83, 90 have been amended. Claims 91-105 have been added. Claims 65-83 and 90-105 are pending and under consideration.

Sections of Title 35, US Code not used in this action can be found in a prior Office action.

The rejection of claims 65-68, 72-83 and 90 under 112, first paragraph for lacking written description is maintained for reasons of record. Claims 91 and 102 are also rejected for the same reasons of record.

(A)As drawn to complexes comprising a bi-functional molecule comprising a binding region of non-antibody origin.

Claims 65-68, 72-83 and 90 are complexes comprising bifunctional molecules wherein said bifunctional molecule is defined as having a binding region of non-antibody origin, and wherein said bi-functional molecules bind to antibodies or to fragments of antibodies The claims encompass a genus of binding regions, with the only attribute required of said binding regions is the binding to an antibody or fragment thereof. The claims are also drawn to a genus of complexes, including complexes formed between the bifunctional molecule and the paratope of said antibodies and fragments and well as complexes formed between the bifunctional molecule and he constant region of said antibody or fragments. The limitation of the bifunctional molecule complexed with an antibody or a fragment thereof imparts neither structural or functional attributes to the binding regions, because the bi-functional molecule can bind to the paratope of the antibody, and it is well known in the art that an antibody can be raised to any peptide, protein or polysaccharide structure. Thus, the genus of binding regions is highly variant because said genus includes any molecule which is itself of non-antibody origin, but can bind to an antibody. The genus includes numerous structural variants from the disclosed antibody binding regions as well as members of the genus which have different functions from the disclosed non-antibody binding regions. the genus would include epitopes of proteins causing antibody production in autoimmune disease, and epitopes of proteins

expressed on cancer cells, and the other non-antibody binding regions, such as the human Fas antigen, as set forth in the art rejection below. The specification provides written description of bifunctional molecules comprising proteins from prokaryotes recognized to bind selectively to antibody constant regions. The specification also provides written description of mouse Fcgamma receptor, and the histidine rich glycoprotein also recognized to bind selectively to antibody constant regions, as well as binding regions encompassing epitopes of infectious agents such as dengue viruses, salmonella viruses, herpes simplex viruses. It is noted that the epitopes of the infectious disease agents would bind to the antibody paratope rather than the antibody constant region. The description of these non-antibody binding regions fails to describe the claimed genus of non-antibody binding regions, because the genus include any protein which is not part of an antibody, to which an antibody binds, and the description of protein A, G, L, Fc gamma receptor and the histidine rich glycoprotein are not representative of this variant genus that would bind to the constant region of the antibody of the first species, nor is the recitation of epitopes of infectious disease agents descriptive of the genus of non-antibody binding region which would bind to the paratope of the antibody of the first species. Further, the genus encompasses the human Fas/Fc fusion protein as complexed with anti-human Fas antibodies as exemplified in the art rejection below. The specification clearly does not provide adequate written description for the broad genus of bifunctional molecules claimed. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed bifunctional molecules.

Applicant has introduced the limitation wherein the bifunctional molecule is bound to a location on the antibody of the first species or to one or more groups provided thereon which does not hinder the binding between the antibody and its specific antigen in order to overcome the above rejection. This has been considered but not found persuasive. The genus of bi-functional molecules described by the specification includes Streptococcal protein G, Staph aureus protein A, and Peptostreptococcus magnus protein L, which bind to antibody constant regions, or domains of the aforesaid proteins which bind to antibody constant regions. The specification also describe avidin as part of a bi-functional molecule which would directly bind to a biotin conjugated antibody. The

genus of bi-functional molecules described by the specification thus include avidin or streptavidin, which would directly bind to biotin, or protein A, protein G or protein L which would bind to the constant region of the antibody of the first species. The genus of bi-functional molecules encompassed by the claims are not limited to bi-functional molecules which bind to biotin, or bi-functional molecules which bind to the antibody constant region. The disclosure of the bi-functional molecules in the specification do not provide an adequate written description for the claimed complexes because the claimed complexes encompass proteins having different structural and functional characteristics from the bi-functional proteins disclosed. Claim 91, is drawn in part to a complex formed between and antibody or a biologically active fragment thereof from a first species and a bifunctional molecule the bifunctional molecule consisting of a binding region or non-antibody origin which binds to the antibody of the first species or to one or more naturally occurring groups provided thereon. Claim 102 is also drawn in part to a bifunctional molecule bound to one or more non-naturally occurring groups provided thereof. The specification provides written description only for biotin as a non-natural group provided on an antibody for binding to a bifunctional molecule comprising streptavidin or avidin. The genus of bi-functional molecules which would bind to a non-natural group on an antibody encompasses proteins and other non-protein molecules having no structural or functional similarity to biotin. Thus the written description of a bifunctional molecule binding to a biotinylated antibody is not an adequate description for the genus of complexes encompassed by the claims. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed invention.

Claims 92-101 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth in the prior office action are withdrawn in light of applicants amendments and arguments.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Translation of JP 64060388, PTO 04-2757.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

6/28/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER

Karen A. Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER